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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/513,086	02/24/2000	Linda S. Mansfield	MSU 4.1-458	4724

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EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/513,086	Applicant(s) MANSFIELD ET AL.	
	Examiner Joseph T. Woitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on October 11, 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 4,13,46 and 50 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,13,46 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 28, 2005 has been entered.

**DETAILED ACTION**

This application filed February 24, 2000, claims benefit to provisional application 60/152,193, filed September 2, 1999.

Applicants amendment filed October 28, 2005, has been received and entered. Claims 1-3, 5-12, 14-45, 47-49 have been canceled. Claims 4, 13, 46 and 50 have been amended. Claims 4, 13, 46 and 50 are pending and currently under examination.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Newly amended claims 4, 13 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Applicants indicate that the prior office action suggested "naturally occurring" protein antigens (amendment page 5, Remarks section), however Examiner can not find this suggestion within the last office action. More importantly, Applicants do not point to support in the specification for the new amendments and in a review of the present specification Examiner can not find support for the instant claim amendments. It appears that the specification would support *inter alia* "consisting" since it does contemplate the two proteins in a composition (for example page 5, lines 1-12). However, the only support for "isolated" is in the context of a recombinant protein (page 9, lines 5-21). Further, there is no literal support for isolating the 16 and 30 kDa proteins directly from *Sarcocystis neurona* as a contemplated part of the invention. To the contrary, a review of the summary of the invention focuses on providing only recombinant proteins in the form of a fusion protein for isolation, as well as using DNA that can encode said fusion proteins, and provides no basis for the present invention to be an isolated protein from *Sarcocystis neurona*. In addition, there does not appear to be support for "naturally occurring" in the context of the claim. While it would not be contested that such forms of the protein exist in nature, the literal support for this embodiment can not be found, in particular in the context of an "antigen" versus the protein itself that exists in nature. Importantly, it would imply non-naturally occurring forms of the protein/antigen which is supported by the present specification at best in the context of a recombinant protein not in the embodiment that some sort of variants of the 16 and 30 kDa proteins were previously encompassed by the claims and taught by the present specification.

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To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 4, 13 and 46 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Claims 4, 13, 46 and 50 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants note the amendment to the claims, in particular the addition of language that clarify that the composition “consisting of” (no longer “comprising of”) and that it is an isolated protein antigen (page 5), and argue that the 16 and 30 kDa proteins are described by their physical properties including a source of the material, not merely by function (page 6).

Applicants point to example 1 in the specification for exemplification of a 2-D gel separation of the protein, and use for generating monoclonal antibodies (page 7) and argue that one of ordinary skill in the art could perform such techniques and obtain isolated forms of the 16 and 30 kDa proteins (page 8). See Applicants’ amendment pages 5-8. Applicants arguments have been fully considered, but not found persuasive.

As noted in the final office action, Examiner acknowledges that Example 1 provides general methodology for two dimensional gel electrophoresis and even without this teaching one of skill in the art would be able to obtain both 16 and 30 kDa proteins from *S. neurona*.

Examiner agrees that methods of electrophoresis and immuno-assays are well known in the art, however this is insufficient to describe relevant structural and functional elements of the claimed product, nor does it provide any guidance to the antigens nor antigenic fragments would provide a form of treatment in the claimed methodology of treating equine. The amendment to the claims are noted (and beyond the new matter rejection set forth above) as indicated in the final office action “at issue is whether the specification even meets the requirements of 35 USC 112, first paragraph, for the isolated forms of the naturally occurring proteins” (see page 3 of the final office action mailed 7/11/2005). Again, a search of the relevant art for disclosure of the specific

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sequences instantly claimed indicate that this is still a subject of research, and that new isolates provide further evidence that variants of the specific sequence are present in nature (see for example Hyun *et al.* Vet Parasitol. 2003 Feb 28;112(1-2):11-20, Sequence comparison of *Sarcocystis neurona* surface antigen from multiple isolates).

Most simply put would be an example where a specific sequence is disclosed and whether the present disclosure provides sufficient description for the skilled artisan to recognize that the sequence was specifically contemplated as the invention. For example, Ellison *et al.* (Int J Parasitol. 2002 Feb;32(2):217-25) Molecular characterization of a major 29 kDa surface antigen of *Sarcocystis neurona*) teaches a protein that meets the size requirements of the protein in the claimed composition, but given the present disclosure clearly the specific sequence of Ellison *et al.* would not have been predicted or even obvious given the present specification. Case law has established that one cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art **as of Applicants effective filing date**. Importantly, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, for the reasons above and of record it is maintained that

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the polypeptide sequences needed to make and use the claimed invention do meet the written description provision of 35 U.S.C. §112, first paragraph.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 13 and 46 rejected under 35 U.S.C. 102(b) as being anticipated by Liang *et al.*  
is withdrawn.

Examiner agrees that Liang *et al.* provides for the disclosure and use of *Sarcocystis neurona* and not isolated forms of the 16 and 30 kDa proteins. While Liang *et al.* teach a composition that comprises both the 16 and 30 kDa antigen of *S. neurona*, and methods where horses were provided this composition, it fails to anticipate the claims as presently amended.

See also Applicants' amendment, pages 8-13.

### ***Conclusion***

No claim is allowed.

It is noted that related application 09/670,355, which is a divisional of the present application and has the same specification, thus provides the same guidance and level of enablement as the present specification, has been abandoned after the BPAI affirming similar rejections as set forth above. It is noted that '355 was directed to polynucleotides and the present



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claims are directed to polypeptides, however the Board recognized that neither the present specification nor the prior art provides the necessary guidance and description to either the nucleic acid or the protein (page 5 of the decision mailed September 30, 2004), affirming the written description and enablement rejections of the Office.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

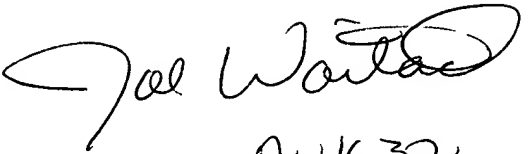
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach



Joel Voitach  
AU 1632

EXHIBIT

**APPENDIX A**

-10-

A vaccine for protecting an equid from a *Sarcocystis neurona* infection comprising a DNA from *Sarcocystis neurona* that encodes at least a 16  $\pm$ 4 kDa antigen and/or 30  $\pm$ 4 kDa antigen of *Sarcocystis neurona*.

-11-

The vaccine of Claim 10 wherein the DNA is operably linked to a promoter to enable transcription of the DNA in a cell of an equid.

-12-

The vaccine of Claim 10 wherein the vaccine is provided in a pharmaceutically accepted carrier.

-18-

A method for vaccinating an equid against a *Sarcocystis neurona* infection comprising:

(a) providing in a carrier solution a DNA from *Sarcocystis neurona* in a plasmid which encodes at least  
5 a 16  $\pm$ 4 kDa antigen and/or 30  $\pm$ 4 kDa antigen of *Sarcocystis neurona*; and

(b) vaccinating the equid with the DNA in the carrier solution.

-19-

The method of Claim 18 wherein the carrier solution is a saline solution.

-20-

The method of Claim 18 wherein the DNA is operably linked to a promoter to enable transcription of the DNA in a cell of the equid.

-44-

A DNA vaccine for an equid comprising a plasmid containing DNA from *Sarcocystis neurona* encoding at least a 16  $\pm$ 4 kDa and/or 30  $\pm$ 4 kDa protein of *Sarcocystis neurona*.

-45-

5 A method for protecting an equid against *Sarcocystis neurona* which comprises providing a vaccine comprising DNA from *Sarcocystis neurona* that when injected into the equid causes the equid to produce antibodies against at least a 16  $\pm$ 4 kDa antigen and/or 30  $\pm$ 4 kDa antigen of the *Sarcocystis neurona* wherein the antibodies prevent infection by the *Sarcocystis neurona*.

-47-

The method of Claim 45 wherein the vaccine is a recombinant virus vector that expresses the 16  $\pm$ 4 kDa antigen and/or 30  $\pm$ 4 kDa antigen.

-48-

The method of Claim 47 wherein the recombinant virus vector is selected from the group consisting of equine herpesvirus, vaccinia virus, canary poxvirus, raccoon poxvirus, and adenovirus.

-49-

The method of Claim 45 wherein the vaccine comprises a DNA plasmid encoding the 16  $\pm$ 4 kDa antigen and/or 30  $\pm$ 4 kDa antigen.

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 13

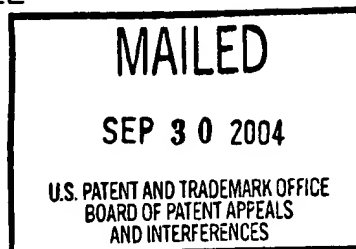
**UNITED STATES PATENT AND TRADEMARK OFFICE**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Ex parte LINDA S. MANSFIELD, MARY G. ROSSANO,  
ALICE J. MURPHY and RUTH VRABLE

Appeal No. 2003-1919  
Application No. 09/670,355

ON BRIEF



Before WILLIAM F. SMITH, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

**DECISION ON APPEAL**

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 10-12, 18-20, 44, 45 and 47-52. Claims 10 and 51 are representative of the subject matter on appeal, and read as follows:

10. A vaccine for protecting an equid from a Sarcocystis neurona infection comprising a DNA from Sarcocystis neurona that encodes at least a  $16 \pm 4$  kDa antigen and/or  $30 \pm 4$  kDa antigen of Sarcocystis neurona.

51. A vaccine composition which comprises an effective immunizing amount of DNA derived from Sarcocystis neurona capable of inducing an antibody immune response, and a pharmacologically acceptable carrier.

Claims 10-12, 18-20, 44, 45 and 47-52 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, i.e., lack of adequate written description. In addition, claims 10-12, 18-20, 44-45 and 47-52 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, i.e., lack of enablement. Finally, claims 51 and 52 stand rejected under 35 U.S.C. § 112, second paragraph. After careful review of the record and consideration of the issues before us, we affirm the rejection of claims 10-12, 18-20, 44-45 and 47-52 under 35 U.S.C. § 112, first paragraph, for lack of adequate written description, and the rejection of claims 51 and 52 under 35 U.S.C. § 112, second paragraph, and decline to reach the merits of the rejection of claims 10-12, 18-20, 44-45 and 47-52 under 35 U.S.C. § 112, first paragraph, for lack enablement.

DISCUSSION

1. Rejection under 35 U.S.C. § 112, first paragraph, written description

Claims 10-12, 1-20, 44, 45 and 47-52 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, i.e., lack of adequate written description.

According to the rejection, "[r]eview of the present specification, the art of record, and a search of the sequence databases for polynucleotides and/or polypeptide sequences of 16(±4) kD antigen and the 30(±4) kD antigen indicate that these sequences have not been identified nor described." Examiner's Answer, page 4. The rejection further contends "the limitation 'at least' in the claims does not limit the invention to 16(±4) kD and/or 30(±4) kD antigen of S. neurona and broadly reads on any antigen that is not disclosed. The specification describes general methods of cloning cDNA sequences from expression libraries; however, the sequences obtained by this method for 16(±4) kD and/or 30(±4) kD antigen are not disclosed." Id. at 4-5. The rejection concludes that "the claimed invention as a whole is not adequately described and is not conventional in the art as of Appellants' effective filing date." Id. at 5 (emphasis in original).



With respect to the issue of conception in the context of an interference count, the Court of Appeals for the Federal Circuit, our reviewing court, has stated that "irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance requires a definition of that substance other than by its functional utility." Fiers v. Revel, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1604 (Fed. Cir. 1993). The court specifically rejected Fiers' argument "that the existence of a workable method for preparing a DNA establishes conception of that material." Id.

In Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1602 (Fed. Cir. 2002), in determining whether or not a claim to a nucleotide sequence met the written description requirement, the court adopted a portion of the Guidelines proffered by the United States Patent and Trademark Office (USPTO). The court stated that:

The written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of characteristics.

Enzo Biochem, 296 F.3d at 1324, 63 USPQ2d at 1613 (citations omitted).

In construing the above requirement, the court in In re Wallach, 378 F.3d 1330, 71 USPQ2d 1939 (Fed. Cir. 2004), recognized "that the written description requirement can in some cases be satisfied by functional description." Id., 378

F.3d at 1335. The court held, however, that

such functional description can be sufficient only if there is also a structure-function relationship known to those of ordinary skill in the art. As we explained above, such a well-known relationship exists between a nucleic acid molecule's structure and its function in encoding a particular amino acid sequence: Given the amino acid sequence, one can determine the chemical structure of all nucleic acid molecules that can serve the function of encoding that sequence. Without that sequence, however, or with only a partial sequence, those structures cannot be determined and the written description requirement is consequently not met.

Id.

In the instant case, as noted by the rejection, neither the disclosure as filed, nor the prior art, discloses any sequence, either amino acid or nucleic, for either the 16(+4) kD and/or 30(+4) kD antigens. Consequently, the written description requirement is not met, and the rejection is affirmed.

Appellants argue with respect to the rejection of claims 10-12, 18-20, 44, 45 and 47-50 that they had "possession of Sarcocystis neurona which contains DNA encoding the 16 +4 and 30 +4 antigens. Thus, the applicants have possession of Sarcocystis neurona DNA encoding the 16 +4 and 30 +4 antigens." Appeal Brief, page 7. Appellants argue further that "[c]onstructing and screening an expression library for clones containing DNA encoding a particular protein is routine in the art," and thus "a person of ordinary skill in the art following the applicants' disclosure would have a high expectation of success of recovering clones from an expression library that express the 16 +4 or 30 +4

antigens using the antibodies against the 16  $\pm$ 4 and 30  $\pm$ 4 antigens prepared as taught in Example 1." Id. at 8.

Appellants' arguments are not convincing. First, the fact that appellants had possession of Sarcocystis neurona is not sufficient to provide possession of DNA that encodes the 16  $\pm$ 4 and 30  $\pm$ 4 antigens. As noted above, even a partial amino acid sequence of the 16  $\pm$ 4 and 30  $\pm$ 4 antigens, which would necessarily require possession of the source of the DNA, i.e., possession of Sarcocystis neurona, would not be sufficient to provide written description support for the claimed DNA encoding the 16  $\pm$ 4 and 30  $\pm$ 4 antigens. In addition, as also discussed above, the existence of a workable method to obtain the DNA sequence is also not sufficient to demonstrate written description support.

With respect to claims 51 and 52, appellants argue that appellants have possession of Sarcocystis neurona DNA, which "would be expected to encode a plurality of antigens, including the 16  $\pm$ 4 and 30  $\pm$ 4 antigens. Therefore, when the DNA is inoculated into a horse, the antigens encoded thereon are expressed in the horse." Appeal Brief, page 10. According to appellants, "[c]laims 51 and 52 do not depend on knowing the DNA sequences encoding the plurality of antigens. The claims merely require that the DNA encode one or more Sarcocystis neurona antigens. Thus, the DNA can be the entire Sarcocystis neurona genome(intact or fragmented) or particular DNA fragments therefrom." Id. at 11.

The above argument is also not found to be convincing. The disclosure as filed does not provide written description support for the use of the entire Sarcocystis neurona genome (intact or fragmented) or particular DNA fragments therefrom as a DNA vaccine. The written description is limited to a "DNA vaccine that contains or expresses at least one epitope of an antigen that has an amino acid sequence substantially similar to a unique 16 (+4kDa) antigen and/or 30 (+4) kDa antigen of Sarcocystis neurona." Specification, page 1 (Field of the Invention); see also pages 5, 17, 24 and 26. Thus, the rejection of claims 51 and 52 under 35 U.S.C. § 112, first paragraph, for lack of adequate written description, is affirmed for the reasons set forth supra with respect to the discussion of claims 10-12, 18-20, 44, 45 and 47-50.

2. Rejection under 35 U.S.C. § 112, second paragraph

Claims 51 and 52 stand rejected under 35 U.S.C. § 112, second paragraph, "as being vague and indefinite in the recitation of 'derived'. Is this DNA isolated from S. neurona?" Examiner's Answer, page 9.

This rejection is affirmed in view of appellants' statement that they will amend the term "derived" to "isolated." See Appeal Brief, page 20.

CONCLUSION

The rejection of claims 10-12, 1-20, 44, 45 and 47-52 under 35 U.S.C. § 112, first paragraph, for lack of adequate written description, and the rejection of claims 51 and 52 under 35 U.S.C. § 112, second paragraph are affirmed. Because we affirm the rejection under 35 U.S.C. § 112, first paragraph, on the

basis of lack of adequate written description, we decline to reach the merits of the rejection under 35 U.S.C. § 112, first paragraph, for lack enablement.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

  
William F. Smith  
Administrative Patent Judge

  
Eric Grimes  
Administrative Patent Judge

  
Lora M. Green  
Administrative Patent Judge

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